UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE PFIZER INC. SECURITIES LITIGATION

04 Civ. 9866 (RO)
(Electronically filed document)

DEFENDANTS' SUR-REPLY MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF THEIR MOTION TO STRIKE

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Defendants Pfizer Inc. ("Pfizer") and Dr. Henry A. McKinnell, Dr. John L. LaMattina, Karen L. Katen, Joseph M. Feczko, M.D. and Gail Cawkwell, M.D. (the "Individual Defendants;" collectively "Defendants") respectfully submit this brief in response to Plaintiffs' Reply ("MTS Reply") Memorandum of Law in Further Support of their Motion to Strike (the "Motion to Strike" or "MTS") Certain Exhibits Attached to the Declaration of Gregory A. Markel ("Markel Declaration") and Related Portions of the Memorandum of Law in Support of Defendants' Motion to Dismiss ("Defendants' Opening Brief") Plaintiffs' Consolidated Class Action Complaint (the "Complaint").

PRELIMINARY STATEMENT

This sur-reply is being filed in response to Plaintiffs' reply in support of their Motion to Strike. It is being submitted because Plaintiffs now seek to strike three exhibits to the Supplemental Markel Declaration in Support of Defendants' Motion to Dismiss ("Supp. Markel Decl.") that Defendants filed concurrently with their Opposition to Plaintiffs' Motion to Strike (Exhibits 45, 48 and 49) and to respond to Plaintiffs' incorrect assertion in their Reply Brief that Pfizer had the discretion to change the Bextra label without the FDA's approval.

In their initial brief in support of their Motion to Strike, Plaintiffs sought to strike Exhibits 1, 1a, 2 and 3 to the Markel Declaration that was filed concurrently with Defendants' Motion to Dismiss. Defendants later filed the Supplemental Markel Declaration with their Reply in Further Support of their Motion to Dismiss to attach exhibits in response to arguments in Plaintiffs' Opposition to Defendants' Motion to Dismiss. The new exhibits included Exhibits 45, 48 and 49, which were submitted solely because Plaintiffs moved to strike Exhibits 1a, 2 and 3. Exhibits 45, 48 and 49 contain the same background information regarding arthritis and the definition of statistical significance as Exhibits 1a, 2, and 3, except that the sources of the new exhibits (FDA material and Pfizer press releases cited in the Complaint) are similar to those that Plaintiffs did not move to strike. Plaintiffs' request that this Court strike Exhibits 45, 48 and 49 should be rejected because these documents can and should be considered by this Court in ruling on Defendants' Motion to Dismiss.

Plaintiffs' contention that it is improper to consider documents that are submitted with a reply brief is wrong. Courts routinely consider documents that are submitted in support of reply briefs or supplemental filings. See, e.g., In re: Unumprovident Corp. Sec. Litig., 396 F. Supp. 2d 858, 875 (E.D. Tenn. 2005) (considering documents attached as appendices to the defendants' reply brief in support of motion to dismiss).

As explained in greater detail below, Exhibit 45, the FDA's Guidance for Industry, Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products ("FDA Guidance for Industry"), should be considered on Defendants' Motion to Dismiss because it is a document published by a federal agency and is capable of accurate and ready determination by resort to the FDA website, a source whose accuracy cannot be reasonably questioned. This Court should also consider the background information regarding arthritis described in Exhibits 48 and 49, two Pfizer press releases, for two reasons. First, these documents are cited in the Complaint. Second, these documents contain well-known information subject to judicial notice.[1] Plaintiffs' assertion that these documents should not be considered because Defendants purportedly are suggesting that their alleged fraudulent misrepresentations or omissions concerning Celebrex or Bextra are warranted by the prevalence of arthritis is absurd. First of all, Defendants made no misrepresentations or omissions. Plaintiffs are simply attempting to distract the Court from the fact that the background information provided in Exhibits 48 and 49 can be judicially noticed. In fact, Plaintiffs do not argue in their brief that Exhibits 45, 48, and 49 are not the types of documents that can be considered on a motion to dismiss. Thus, Plaintiffs' Motion to Strike should be denied.

[1] In Defendants' Opposition to the Motion to Strike, Defendants withdrew their request that the Court consider Exhibits 2 and 3 to the Markel Declaration, two fact sheets regarding arthritis that are on the website of the Centers for Disease Control and Prevention, and respectfully requested that this Court replace the paragraph in the Opening brief citing this material (Def. Br. at p.3) with a new, similar paragraph based on the allegations of the Complaint and Supplemental Markel Declaration Exhibits 48 and 49, two press releases cited in the Complaint. Def. MTS Opp. at 16-17. Defendants submitted these new exhibits because Plaintiffs had not moved to strike any of the numerous press releases cited in the Complaint that Defendants attached to the Markel Declaration submitted concurrently with Defendants' Motion to Dismiss brief.

ARGUMENT

I. The FDA Document Explaining that 5% is the Conventional Threshold for Statistical Significance May Be Considered by the Court Because it is an FDA Document Published on the FDA's Website

Exhibit 45, which is the FDA Guidance for Industry, may be considered by the Court in deciding Defendants' motion to dismiss because it is a document published by the FDA, a federal agency, on its official website and therefore "capable of accurate and ready determination by resort to sources whose accuracy cannot be reasonably questioned." See Fed. R. Evid. 201. Courts regularly take judicial notice of such documents. For example, in Wellbutrin Sr/Zyban Antitrust Litigation, the court took judicial notice of the contents of an FDA report that was posted on the official FDA website. 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003); see also Oxford Asset Mgmt., Ltd. v. Jaharis, 297 F.3d 1182, 1189 (11th Cir. 2002) (affirming district court's consideration of a drug's label that was part of the FDA's public file); Cali v. E. Coast Aviation Servs. Ltd., 178 F. Supp. 2d 276, 287 (E.D.N.Y. 2001) (taking judicial notice of web pages from Pennsylvania state agencies and the Federal Aviation Association). Notably, Plaintiffs did not move to strike any of the FDA documents available on the FDA's website that Defendants submitted with their Opening Brief in support of their Motion to Dismiss. See, e.g., Markel Decl. Exs. 5, 8, 9, 13, 14, 17, 19.

Defendants submitted the FDA Guidance for Industry concurrently with their reply brief because Plaintiffs had moved to strike Exhibit 1a, which also defines the term statistical significance. Exhibit 1a is the definition of statistical significance from the Primer on Statistical Significance and P Values published by the American College of Physicians in Effective Clinical Practice, a medical journal. It states that if the "probability that the observed result [of a study] is due to chance" is "less than 5%, researchers typically assert that the findings are 'statistically significant.'" Markel Decl. Ex. 1a. Although a definition of statistical significance is not essential to Defendants' arguments for dismissal of Plaintiffs' Complaint, Defendants included the definition in their motion to dismiss brief because it is a term used in the Second Circuit's decisions in the Carter-Wallace cases. The Carter-Wallace decisions, which established the standard for disclosing adverse events that occur during the use of a drug and for pleading scienter with respect to alleged failures to disclose such adverse events, do not include a definition of statistical significance. See

Defendants' Opposition to Plaintiffs' Motion to Strike, dated August 2, 2006 ("Def. MTS Opp.") at 14. As explained in Defendants' Opposition to Plaintiffs' Motion to Strike, this Court may properly take judicial notice of the definition of statistical significance in the Primer because it is a standard reference work. Def. MTS Opp. at 14-15. Plaintiffs do not dispute that it is appropriate for courts to take judicial notice of information, including definitions, in standard reference works. Like Exhibit 1a, the FDA Guidance for Industry states that 5% is the "conventional level[ ] of statistical significance." Supp. Markel Decl. Ex. 45 at 5 & n.5. Defendants submitted Exhibit 45 with their reply brief because Plaintiffs had not previously moved to strike FDA documents, and Exhibit 45 repeated information included in Exhibit 1a.

Plaintiffs' assertion that Exhibits 1a and 45 create a "factual dispute on the appropriate measure for determining 'statistical significance'" that precludes dismissal fails. MTS Reply at 14. If Plaintiffs' argument were accepted, courts could never decide cases regarding the duty to disclose adverse events experienced by patients taking a drug on a motion to dismiss. This is contrary to Carter-Wallace, in which the Second Circuit established that statistically significant evidence of a causal connection between an adverse event and a drug is the pleading standard for disclosing such an event. In fact, the Second Circuit affirmed the dismissal of the Section 10(b) claims on a motion to dismiss in Carter-Wallace, finding that the defendants had no duty to disclose and therefore did not act recklessly in failing to disclose adverse events experienced by patients taking a drug at a point in time when there was no statistically significant evidence of a causal connection between the drug and the adverse events. See In re Carter-Wallace, Inc. Sec. Litig., 150 F.3d 153 (2d Cir. 1998) ("Carter-Wallace I"); In re Carter-Wallace, Inc. Sec. Litig., 220 F.3d 36 (2d Cir. 2000) ("Carter-Wallace II"; collectively, "Carter-Wallace"); see also Def. MTD Reply at 9, 22-23; Def. Br. at 22-27; 31-48. The cases that Plaintiffs cite to support their assertion that statistical significance is a fact issue are inapposite because they are not from the Second Circuit, do not purport to follow Carter-Wallace, and do not involve a pharmaceutical manufacturer's duty to disclose information

regarding its drugs.[2]

Moreover, there is no "factual dispute" concerning the conventional level of statistical significance that precludes dismissal. Defendants cited Exhibit 1a for the definition that if the "probability that the observed result [of a study] is due to chance" is "less than 5%, researchers typically assert that the findings are statistically significant." Markel Decl. Ex. 1a; see also Def. Br. at 2 n.1; Def. MTS Opp. at 5-6. Plaintiffs do not provide a different definition. Plaintiffs' citation to McNeil-P.P.C., Inc. v. Bristol-Myers Squibb Co., is unavailing because the court in that case defined "statistical significance" in the same way as the documents that Defendants cite.[3] In McNeil, the court stated that "[r]esults are statistically significant when it is ninety-five percent certain that the results are not due to chance." 755 F. Supp. 1206, 1214 n.7 (S.D.N.Y. 1990), aff'd, 938 F.2d 1544 (2d Cir. 1991); see also Markel Decl. Ex. 1a; Supp. Markel Decl. Ex. 45. This is the same as saying as that results are statistically significant where there is a 5% probability that they are due to chance.

Plaintiffs' reliance on the label for Lipitor, one of Pfizer's cholesterol-reducing drugs, as support for their argument that there is a factual dispute regarding the typical level of statistical significance, is misplaced. First, as previously noted, the Carter-Wallace decisions foreclose this argument. Second, contrary to Plaintiffs' assertion, the Lipitor label does not state that 2% was the threshold for statistical significance used in evaluating the adverse events that occurred during clinical trials of Lipitor. Rather, the Lipitor label merely lists adverse events that occurred, in clinical trials, "regardless of causality assessment," at a rate of 2%, and does not state that this rate is statistically significant. Second Supp. Markel Decl. Ex. 50 (Lipitor Label) at 21. Indeed, the

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[2] See MTS Reply at 4 n.4; Arnold v. City of York, No. Civ.A. 4:03-1352, 2004 WL 2331781, at *5 (M.D. Pa. June 28, 2004); Roberts v. United States, 947 F. Supp. 282, 289 (E.D. Tex. 1996).

[3] Plaintiffs cite McNeil to support their assertion that the determination of statistical significance "often involves a battle of the experts." MTS Reply at 13. McNeil is inapposite because it did not involve federal securities claims, but rather a claim that the defendant falsely advertised that its drug was superior to the plaintiff's drug. Further, it concerned a request for injunctive relief, not a motion to dismiss, and did not address the pleading standard for claims regarding the duty to disclose adverse events that occur in patients taking a drug. See McNeil, 755 F. Supp. at 1219. In addition, it pre-dates the Carter-Wallace decisions, in which the Second Circuit established statistically significant evidence of a causal connection between the drug and the event as the pleading standard for such claims.

only reference to statistical significance in the Lipitor label is a notation that the 5% threshold was used as the threshold level of statistical significance in clinical studies of Lipitor.[4] Id. at 9, nn.1, a, b, c (Lipitor Label) (indicating that significant differences are those with $p \leq 0.05$).[5]

Regardless, Defendants are not arguing that "a 5% probability is 'statistically significant' as a matter of law." See MTS Reply at 1. Although the 5% threshold is the typical convention used, see, e.g., McNeil-P.P.C., 755 F. Supp. at 1214 n.7, the exact threshold that is conventional matters little, because all of the studies at issue in this case used the 5% threshold. See Def. MTS Opp. at 15 & n.19. Moreover, Plaintiffs do not and cannot contest that statistical significance is determined by consideration of the "probability that the observed result [of a study] is due to chance." See MTS Reply at 1-2, 12-14.[6]

Finally, Plaintiffs disingenuously and inaccurately claim that the withdrawal of Bextra from the market and the insertion of the black box warning in the Celebrex label is "the best evidence that the adverse findings of CLASS, CABG Trial 35 and the 1999 Study were 'statistically significant.'" MTS Reply at 15-16. As described in Defendants' Motion to Dismiss and Reply, the Alzheimer's 001, CLASS, and CABG Trial 35 studies did not demonstrate statistically significant evidence of a causal connection between Celebrex and Bextra and cardiovascular events. See Def. Br. at 22-25, 33-39, 39-41, 44-45; Def. MTD Reply at 7-14, 24-26, 27-30, 34-35. Indeed, when the FDA received these studies, it drew no such conclusion and took no action, such as issue a warning or require a label change. See Def. MTD Reply at 14-17. Further, Plaintiffs also ignore the fact

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[4] The Lipitor label is publicly available at http://www.fda.gov/cder/foi/label/2006/020702s044lbl.pdf.

[5] Plaintiffs' assertion that Plaintiffs "do not contend that the Court should, at this time, consider Pfizer's prescribing information for Lipitor" fails because by citing the Lipitor label, Plaintiffs have asked the Court to consider it. See MTS Reply at 13. Defendants have submitted the Lipitor label to show the Court that is does not state what Plaintiffs claim it states. The Court may consider the Lipitor label because it is cited in Plaintiffs' reply brief, it is part of the FDA's public file on Lipitor and it is available on the FDA's website. See Oxford, 297 F.3d at 1189 (affirming district court's consideration of a drug's label that was part of the FDA's public file).

[6] Straining to show that the FDA's reference to 5% as the typical measure of statistical significance does not apply here, Plaintiffs argue that Exhibit 45 raises a factual issue as to whether the 5% threshold applies to the safety results of clinical trials as well as to efficacy results. See MTS Reply at 16. Plaintiffs note that the FDA discussed the efficacy of drugs in Exhibit 45. Plaintiffs fail to demonstrate that the FDA uses a different threshold for determining the statistical significance of safety results. Thus, Plaintiffs' attempt to create a fact issue where none exists fails.

that the withdrawal of Bextra and the insertion of the black box warning in the Celebrex label occurred in 2005, well after these three studies were provided to the FDA, and only after the results of later studies, such as the APC trial, became available. See Def. Br. at 6-11; Cplt. ¶ 127.[7]

Also unavailing is Plaintiffs' incorrect argument that Exhibit 45 should be stricken because "the submission of a new exhibit [is] improper on a reply." MTS Reply at 16. Plaintiffs do not cite a single case which supports this proposition, nor can they. Courts routinely consider exhibits provided in connection with reply briefs or supplemental filings.[8] In any event, Exhibits 45, 48 and 49 were submitted only because Plaintiffs moved to strike Exhibits 1a, 2 and 3, which contain similar background material.

The single case that Plaintiffs cite in support of their argument that it is inappropriate to submit new exhibits on a reply brief is inapposite. The court in Selby v. Principal Mutual Life Insurance Company, No. 98 Civ. 5283 (RLC), 2000 WL 1863760, at *4 (S.D.N.Y. Dec. 20, 2000) did not even address the issue. Rather, it considered whether defendants could raise new facts in opposition to a motion, pursuant to Federal Rule of Civil Procedure 60(b)(2), for reconsideration of a class certification order. The court noted that "the defendant had ample opportunity to bring any new facts mentioned in the [plaintiffs'] reply brief to the court's attention, and to request additional

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[7] Equally futile is Plaintiffs' assertion that a purported 2% drop in the price of Pfizer stock following the disclosure of the results of CABG Trial 35 shows that the results of that study were "significant." See MTS Reply at 14-15. Contrary to Plaintiffs' contention, the results of CABG Trial 35 were not publicly announced for the first time in a press release on October 15, 2004. Rather, as described in Defendants' Motion to Dismiss and Reply, they were disclosed more than a year earlier in an article in the Journal of Thoracic and Cardiovascular Surgery. See Markel Decl. Ex. 29; Def. Br. at 30, 55; Def. MTD Reply at 35 n. 67. Following the withdrawal of Vioxx from the market, Pfizer issued a press release on October 15, 2004 noting that Pfizer would be conducting further studies regarding Bextra's long-term cardiovascular safety profile. Although the press release disclosed that in two clinical trials of patients undergoing coronary artery bypass graft ("CABG") surgery, an increase in cardiovascular events was observed in patients who received Bextra, it also noted that the results of the first CABG study had been published the previous year. See Supp. Markel Decl. Ex. 46 (Press Release). Accordingly, Plaintiffs' assertion that the disclosure of the results of CABG Trial 35 was followed by a decline in Pfizer's stock price fails.

[8] See, e.g., In re: Unumprovident Corp., 396 F. Supp. 2d at 875 (considering documents attached as appendices to the defendants' reply brief); In re Skechers U.S.A., Inc. Sec. Litig., No. CV 03-02094, PA, 2004 WL 1080174, at *2 n.2 (C.D. Cal. May 7, 2004) (taking judicial notice of documents attached to "the Declaration and Supplemental Declaration"); In re Verifone Sec. Litig., 784 F. Supp. 1471, 1475 n.2 (N.D. Cal. 1992) (taking judicial notice of exhibit to supplemental declaration), aff'd 11 F.3d 865 (9th Cir. 1993); Medoil Corp. v. Citicorp, 729 F. Supp. 1456, 1458-1459 (S.D.N.Y. 1990) (considering an exhibit to defendant's reply brief).

time to challenge them before an opinion was issued." Id. The court also stated that "[w]hile raising a new substantive issue of law for the first time in a reply is improper, plaintiffs are not guilty of this impropriety." Id. at 4 n.9. Here, Defendants did not raise new issues of law or fact in Exhibits 45, 48 and 49, but rather presented alternative or additional cites for the same material that they submitted in exhibits to their motion to dismiss. Thus, it is entirely appropriate for the Court to consider these documents. Finally, since this is not a motion for reconsideration pursuant to Rule 60(b)(2), but rather a further response to Plaintiffs' Motion to Strike, the standard applicable to the motion in Selby does not apply here.[9]

II. The FDA Requires a Drug Manufacturer to Use the Verbatim Language Approved by the FDA for its Prescription Drug Labels

Plaintiffs argue that the Court should strike the draft Bextra label included in Exhibit 1 to the Markel Declaration. MTS Reply at 8-12. As described in Defendants' Opposition to Plaintiffs' Motion to Strike, however, it is proper for the Court to consider the excerpts of the Bextra NDA, including the draft proposed label for Bextra that Pfizer submitted to the FDA in the Bextra NDA, in deciding Defendants' Motion to Dismiss. See Def. MTS Opp. at 7-13. The Bextra NDA is referenced in the Complaint and the draft Bextra label included therein is integral to Plaintiffs' claims regarding the redaction of the Bextra label. Thus, the draft label should be considered.

Defendants submit this sur-reply in response to Plaintiffs' incorrect assertion that this Court should reject Defendants' contention that this draft label supports Defendants' assertion that Pfizer was required by law to use the Bextra label as approved by the FDA without alteration. MTS Reply at 9-10; See Def. MTD Reply at 13. In their Reply, Plaintiffs assert that Pfizer could have included additional warnings about the purported increased cardiovascular risk associated with Bextra in the Bextra label. MTS Reply at 9-12. To the contrary, Pfizer was required to use the Bextra label that the FDA approved. The cases that Plaintiffs cite to support their point that Pfizer could have unilaterally added warnings to the Bextra label all pre-date the FDA's announcement of its position

[9] Rule 60(b)(2) provides that a court may reconsider a final judgment or order where there is "newly discovered evidence which by due diligence could not have been discovered in time to move for a new trial under Rule 59(b)."

that a drug manufacturer cannot change a drug label without FDA approval. See MTS Reply at 10-12. In the Preamble to its recent rule regarding drug labeling, the FDA stated that it interprets the FDCA to "establish both a 'floor' and a 'ceiling,' such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading." Final Rule, Requirements on Content & Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) ("Final Rule").

One court recently noted that "[r]egarding the argument that manufacturers can modify labels without FDA approval, the FDA urges that 'in practice, manufacturers typically consult with FDA before doing so to avoid implementing labeling changes with which the agency ultimately might disagree.'" Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 529 (E.D. Pa. 2006) (quoting Final Rule, 71 Fed. Reg. at 3934-3935. The court concluded that unilateral changes by a drug manufacturer to a label are not allowed, noting that "the FDA is 'uniquely qualified' to interpret the regulations which it is entrusted by Congress to administer." Id. at 537. The court agreed with the FDA's position that "there is no statutory or regulatory provision permitting the manufacturer to make a labeling change to its generic drug without prior FDA approval." Id. (citing FDA Amicus Brief). Any deviation from the approved label would render the label "false and misleading," and thereby misbrand the drug in violation of the FDCA. Id. at 528. In short, drug manufacturers must "use verbatim the language" that the FDA approves. Id. at 537.

Courts have found that the FDA's position with regard to its control of drug labeling and its view that state laws regarding drug labeling are preempted by the FDCA are entitled to deference. Accordingly, they dismiss claims that drug manufacturers failed to include certain warnings in their drug labels. For example, with respect to the inclusion of cardiovascular warnings on the Celebrex and Bextra labels, a court recently dismissed state law failure to warn claims against Pfizer as preempted by the FDCA. See In re Bextra and Celebrex Mktg. Sales Practices & Prod. Liability Litig., No. M: 05-1699 CRB, 2006 WL 2472484, at *3 (N.D. Cal. Aug. 24, 2006); In re Bextra and Celebrex Mktg. Sales Practices & Prod. Liability Litig., No. M: 05-1699 CRB, 2006 WL 2374742,

at *10 (N.D. Cal. Aug. 16, 2006); see also Colacicco, 432 F. Supp. 2d at 538 (dismissing state law claims that defendant drug manufacturer failed to warn of an increased risk of suicide associated with its anti-depressant as preempted by the FDCA); Colacicco, 432 F. Supp. 2d at 529 ("it is abundantly clear that the FDA's position is entitled to significant deference").

Plaintiffs acknowledge the Colacicco court's conclusion regarding preemption, but claim that it represents "[a] minority view." See MTS Reply at 12 n.10. Plaintiffs' assertion is incorrect because the cases to which Plaintiffs compare Colacicco precede and do not address the Preamble to the Final Rule. The recent decisions in Colacicco and In re Bextra and Celebrex Marketing both addressed the FDA's position regarding its control over drug labeling, as set forth in the Preamble to its recent Final Rule, and agree that the FDA controls drug labels and the FDCA preempts state law failure to warn claims. Pursuant to the Preamble to the Final Rule, Colacicco and the In re Bextra and Celebrex Marketing decisions, it is clear that Pfizer did not have the ability to change the Bextra label and was required to use the label that the FDA approved. Further, as described in Defendants' Reply Brief, even though many of Plaintiffs' claims are federal claims and therefore are not preempted by the FDCA, all of Plaintiffs' claims with respect to warnings on the Bextra and Celebrex labels should be dismissed as precluded by the FDCA because the FDA is the ultimate authority in charge of drug labeling. See Reply at 41-44.

III. Supplemental Markel Declaration Exhibits 48 and 49 May Be Properly Considered Because They are Cited in the Complaint and Recite Accurate, Well-Known Facts

Plaintiffs also seek to strike the well-known arthritis facts described in two Pfizer press releases attached to the Supplemental Markel Declaration as Exhibits 48 and 49. Defendants submitted these exhibits concurrently with their Reply Brief because Plaintiffs objected to exhibits containing similar information that Defendants submitted with their Motion to Dismiss, and Plaintiffs had not objected to Defendants' request that the Court consider other Pfizer press releases that are cited in the Complaint. See Markel Decl. Ex. 20; Supp. Markel Decl. Ex. 42. Defendants did not provide Exhibits 48 and 49 in connection with their reply to support a new point. Plaintiffs do not contest that these documents are appropriate for consideration by the Court because they are quoted in the Complaint. See Cplt. ¶¶ 161, 178; Def. MTS Opp. at 16-17. Further, Plaintiffs do not

dispute that Exhibits 48 and 49 are appropriate subjects for judicial notice or contest the accuracy of the statements regarding arthritis or that the facts are well-known. See Def. MTS Opp at 17 n.21. Instead, they assert that the Court should not consider the documents because Defendants purportedly are using them to show that the alleged misrepresentations and omissions are "warranted given the prevalence of arthritis affecting Americans." MTS Reply at 16-17. Defendants are making no such argument, because Defendants made no misrepresentations or omissions. Defendants merely provided information about arthritis as background material that can be considered on Defendants' Motion to Dismiss.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that Plaintiffs' Motion to Strike Exhibits 1, 1a, 45, 48 and 49 be denied.

Dated: New York, New York
September 11, 2006

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